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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,724	09/08/1999	GERLINDE LENZEN	045636-5025	3497

9629 7590 04/26/2006  
MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1649

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/319,724		LENZEN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Michael Brannock		1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23,25,26 and 29-46 is/are pending in the application.
- 4a) Of the above claim(s) 30-32,38,43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 23,25,26,29,33-37,40,42 and 46 is/are allowed.
- 6) ☐ Claim(s) 39,41 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application: Claims and Amendments***

Applicant is notified that the amendments put forth on 11/23/05, have been entered in full. Due to the rejoinder of previously withdrawn process claims, see below, the finality of the previous office action is withdrawn. It is noted that a Notice of Appeal and Appeal Brief have been filed. Applicant can request a refund for the associated fees or leave it as credit for future appeals.

### ***Response to Amendment***

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Claims 23, 25, 26, 29, 33-37 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 40, 41, 42, 45, 46, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claim 40, 41, 42, 45, 46 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 30, 31, 32, 38, 43, 44, not directed to the process of making or using the patentable product, will not be rejoined.

Art Unit: 1649

**New Rejections:**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 41, 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons.

Claim 39 recites the goal of assaying a substance for agonist or antagonist activity towards the polypeptide of claim 23, yet the claim does not provide a step or steps that clearly indicate how this goal is to be accomplished. Specifically, the claim does not set forth what result of the measurement identifies the substance as an agonist and what result of the measurement identifies the compound as an antagonist.

Additionally the phrase “said polypeptide binding sites” lacks antecedent basis in the claim; thus an artisan would not know which polypeptide binding sites are the said polypeptide binding sites.

Furthermore, the claim requires measuring inhibition of chemotaxis, yet the claim does not specify what is supposed to be chemotactic.

Claim 41(a) requires “extracting membrane proteins corresponding to said isolated polypeptide”, yet the neither the specification nor the claims stipulate how the membrane proteins should correspond to the isolated polypeptide. It is suggested to Applicant that the

Art Unit: 1649

following phrase would obviate this part of the rejection: 41(a) “extracting membrane proteins comprising the amino acid sequence of said isolated polypeptide”

Claim 41(c) requires measuring the quantity of said compound bound to said isolated polypeptide, yet the claim does not appear contain a step that binds the compound to the isolated polypeptide, rather it appears that the compound is bound to the “membrane proteins corresponding to said isolated polypeptide”, as in 41(b). Thus, it is unclear if additional steps are required to accomplish the goal of 41(c) or that the literal meaning of 41(c) was not applicant’s intended meaning.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assaying for agonists and antagonists of the polypeptide of claim 23 by measuring eosinophil chemotaxis, does not reasonably provide enablement for such method measuring any other chemotaxis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass all manner of chemotaxis. The specification teaches that the polypeptides of SEQ ID NO: 1 and 14 mediate eosinophil chemotaxis and nowhere in the specification does the specification teach that other cell types or organisms undergo changes in chemotactic behavior in response to agonists or antagonist of the polypeptides of SEQ ID NO: 1

Art Unit: 1649

and 14. It may eventually be true that other cell types will be found to respond as such, yet the specification has provided no guidance as to which should be used. Thus the teaching in the specification is not commensurate with that which is claimed.

Therefore due to the large quantity of experimentation to randomly sample the vast repertoire of known examples of biological chemotactic activity, the lack of direction/guidance presented in the specification regarding which cell types other than eosinophils could be used, and the absence of working examples directed to same, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



April 17, 2006



ELIZABETH KEMMERER  
PRIMARY EXAMINER